UNIVERSITY of MARYLAND
MEDICAL SYSTEM

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CORPORATE OFFICE

December 24, 2013

The Honorable Martin O'Malley
Governor of the State of Maryland
State House
100 State Circle
Annapolis, Maryland 21401

The Honorable Peter A. Hammen
Chairman
Health and Government Operations Committee
The Maryland House of Delegates
6 Bladen Street, Room 241
Annapolis, Maryland 21401

The Honorable Thomas M. Middleton
Chairman
Senate Finance Committee
Miller Senate Office Building, 3 East Wing
11 Bladen Street
Annapolis, Maryland 21401

RE: **Maryland Health Care Commission (MHCC) Recommendations on Implementation of Health-General §19-121.1 (Senate Bill 750/House Bill 1141-2012 Session)**

Dear Governor O'Malley, Chairman Middleton, and Chairman Hammen:

This letter is offered on behalf of the University of Maryland Medical System (UMMS), as you conduct your review of the proposed regulations submitted by the MHCC regarding specialized cardiovascular services. Pursuant to Health-General Section 19-121.1, the MHCC was required to report its recommendations for the regulations to you before they are implemented.

In October, 2013, the MHCC provided a Draft for Informal Public Comment. UMMS provided extensive comments during the informal comment period. A copy of those comments, dated October 21, 2013, is attached and incorporated herein. Subsequent to the informal comment period the MHCC revised the proposed regulations and submitted a copy to you for review over 60 days. Following your review and comments, the MHCC proposes to set forth a third draft.

While many, if not most, of UMMS' comments in the October 21st letter still pertain, this cover highlights the most grave concerns and some of the most extensive changes between the informal draft and the copy submitted to you. In essence, the revised draft is a substantial departure from the recommendations made by the Clinical Advisory Committee (CAG). It substantially removes significant review and consideration deemed important to programs under review. This latest draft would force programs to consent to "voluntary relinquishment" as a pre-condition to obtaining or maintaining the authority to operate either a cardiac surgery program or a PCI program. It also creates additional trigger points for program closure, beyond those recommended by the CAG, and mandates program closure upon notice from the Executive Director, if these "new" triggers are reached.

The CAG devoted considerable time to the concept that cardiovascular programs should be reviewed and evaluated based upon quality and that volume alone is not determinative of quality. The CAG also recommended that "[f]ocused reviews of programs should be conducted based on triggers recommended by the CAG, (Report of the Clinical Advisory Group on Cardiac Surgery and PCI Services, Final Report, June 2013, pg. 7) and that "[b]oth cardiac surgery and PCI programs should be given an opportunity to address deficiencies identified before program closure is ordered by the Commission. Id. at 9, emphasis added. Specifically with regard to program closure, the CAG recommended:

> Program closure should be considered for cardiac surgery programs with a one star composite rating for coronary artery bypass graft (CABG) surgery using the rating scale developed by STS-ACSD for four consecutive six-month reporting periods or cardiac surgery case volume of less than 100 for two consecutive years. Id., emphasis added.

Nonetheless, the current iteration of the proposed regulations would not, for instance, allow an opportunity to address deficiencies at these junctures. Proposed Md. Code Regs. 10.24.17.04B, pg. 10. Additionally, if a cardiac surgery program falls below 100 cases in a given year, the program will be subject to a focused review, (10.24.17.07B(2) and 10.24.17.04B(5)(c) pps. 20 and 21, respectively) and may in short order be shut down should the MHCC request that the hospital voluntarily "relinquish its authority and close its cardiac surgery services..." 10.24.17.04B(5)(f). Similar provisions exist regarding PCI programs as well. Indeed pursuant to this iteration of the proposed regulations, any program, cardiac surgery or PCI, may be required to voluntarily relinquish its authority to operate if, following a very limited opportunity to cure, notice is given by the MHCC.

The MHCC sets forth that "[o]n} balance, the draft Chapter provides more opportunity and flexibility than the current Chapter for hospitals to present the Commission with proposals for changing the number of cardiac surgery programs in the State". New provisions have been inserted which address when the impact of a new cardiac surgery program on existing programs will be considered. The proposed changes should, but do not, reflect consideration of the impact on all existing programs. 10.24.17.05(2), pg. 12. Rather than include consideration of the impact of a new cardiac surgery program on all existing programs in the same or adjacent region(s), the new proposed regulations propose considering the impact on programs with volume above a certain threshold in a given year.

Because the changes in this draft are substantial as are the import and the potential impact on hospitals, UMMS would urge very careful consideration of what is being proposed and dialogue amongst the stakeholders. The services governed by these regulations are high end and are critical to the communities where they are located. Regulation is important; yet, it should be proposed (1) following the guidance of the Clinical Advisory Committee and (2) reasonably, taking into account practical and individual circumstances impacting programs, patients and communities.

Thank you for your consideration.

Sincerely

Donna L. Jacobs, Esq.
Senior Vice President
University of Maryland Medical System

Attachment

cc: Ben Steffen
Secretary Joshua Sharfstein
David Smulski
Linda Stahr

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CORPORATE OFFICE

October 21, 2013

Via Email: Eileen.fleck@maryland.gov

Eileen Fleck
Chief, Acute Care Policy & Planning
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

RE: **Comments regarding the State Health Plan For Facilities and Services: Specialized Cardiovascular Services—COMAR 10.24.17**

Dear Ms. Fleck:

Thank you for the opportunity to provide comments on the informal, draft proposed regulations for cardiovascular services. Proposed Md. Code Regs. 10.24.17.et. seq. These comments are provided on behalf of the hospitals which are part of the University of Maryland Medical System ("UMMS").

First, let me commend the MHCC for the time and attention devoted to this issue throughout the 2012 legislative session, throughout the meetings with the Clinical Advisory Committee and, up to and, including the draft of these proposed regulations. This draft reflects thoughtful consideration of the construct of the 2012 law. The comments included herein are intended to be constructive and further support the intent of the legislation and ensure the efficient, effective operation of quality cardiovascular services programs in Maryland.

Additional Consideration for Existing Primary PCI Programs

In general, the proposed regulations track the recent statutory modifications. They do not, however, address the favorable consideration that is to be given to hospitals with emergency PCI programs that seek to expand. The 2012 law requires that the regulations shall "give weight to the experience, performance, investment, and scope of interventional capabilities of an applicant hospital that was performing emergency PCI on January 1, 2012" when the hospital applies for a Certificate of Conformance. MD. ANNOTATED CODE, HEALTH-GEN. II, §19-120.1(g)(2)(xi)(2012). The proposed regulations should be expanded to incorporate these weighted measures.

Effective Dates

UMMS fully supports the provision to make the effective date of these regulations prospective vis-à-vis any application or letter of intent. Proposed Md. Code Regs. 10.24.17.02E, pg.4. Similarly, UMMS suggests that since the standards for cardiac surgery, i.e. STS-ACSD Star ratings and the 100 case thresholds, Proposed Md. Code Regs. 10.24.17.04B, pg. 12 and 10.24.17.07A(5), pg. 24, are new suggestions, they too should be applied prospectively. At present, there are no minimal standards for performance and any measures of such should be applied moving forward, not backward, after the effective date of the regulations. Therefore, UMMS recommends that the MHCC set forth the clear expectation that hospitals will begin to collect data for the STS-ACSD star ratings and to strive for minimum volume standards as of the effective date of the final regulations. This will ensure that the MHCC will only seek hospital compliance with these new standards as of the Effective Date.

The MHCC recommends that "[g]iven the uncertainty regarding reform of the all-payer system in Maryland..., the approval of new cardiac surgery or new PCI programs that require capital investment by hospitals should be delayed until more certainty is assured concerning how hospitals will be reimbursed for services." Proposed Md. Code Regs. 10.24.17.03, Issues and Policies, Cost of Care, pg. 7. UMMS would oppose such a delay with regard to expanding a PCI program to include elective PCI. The time frame to achieve "certainty" about the impact of the waiver is nebulous at best and potentially quite a distance down the road. A few hospitals have sustained primary PCI programs without an elective PCI program for extended periods of time, at great financial cost, and without the opportunity to spread the infrastructure burden across an elective PCI program. These hospitals have operated successful primary PCI programs but have long awaited the opportunity to expand the program to include elective PCI. Expansion to include an elective PCI program benefits the hospitals and the communities they hospitals serve.

We recognize that there may be additional capital costs associated with the expansion of a PCI program. However, the MHCC can evaluate the impact of those costs on an individual hospital basis when a new elective PCI program is considered. Moreover, at present, there are added costs to the overall care of the population when a hospital with primary PCI has to transfer patients who have had cardiac catheterizations or STEMI procedures in the lab and have been found to need additional intervention. In the case of STEMI patients, the hospital can treat the lesion that is creating the heart attack, but if there are additional areas that should be addressed, but do not fit the current approved primary PCI program criteria for intervention, these patients have to be transferred to another facility, creating additional cost to the health care system as well as additional risk for the patient. Approval for an elective PCI program will reduce these transfer-related costs and expense to the overall cost of care in Maryland. New, elective PCI programs should be evaluated and permitted to proceed, where appropriate, without further, undue delay.

Limited Numbers of Programs and Health Planning Regions

The Clinical Advisory Committee (CAG) discussed at length the preferred strategy and philosophy of measuring programs by the quality of each individual program. In that vein, any language regarding the limitation of services should be removed. This includes "the public is best served if a limited number of hospitals provide specialized services to a substantial regional population base" and the following sentence. Proposed Md. Code Regs. 10.24.17.03, Specialized Hospital Services, pg. 10.

That same section seeks to modify and consolidate the state's health planning regions for cardiac surgery and PCI services. This change would create distinct and separate health planning regions just for specialized cardiovascular services. Orderly, well-organized state health planning demands uniform planning regions statewide for all services within the state. The planning regions should continue as currently delineated.

Clinical Advisory Committee

UMMS supports the recommendation that the CAG continue to provide policy advice to the MHCC regarding appropriate standards for high quality specialized cardiovascular services. Proposed Md. Code Regs. 10.24.17.03, Policy Guidance, pg. 10. The scope of the role of the CAG should extend further to include participation in any focused review or program analysis related to compliance with clinical standards and performance measures including obtaining and maintaining Certificates of On-going Performance for cardiac surgery and PCI programs. The clinical expertise of the CAG would be instructive and instrumental to the review of the quality of cardiac surgery and PCI programs under the regulations.

New Cardiac Surgery Programs

Proposed Md. Code Regs. Section 10.24.17.04(A)(1)(b), pg. 11, requires one full year of reporting on quality measures recommended by the CAG Advisory Subcommittee. There is no suggestion, however, as to the type of data sought here. Subsection (d) suggests it would be the data related to the primary and elective PCI services which are requisite before a CON could be granted but that is not entirely clear. The MHCC should clarify the type of quality data that is contemplated.

New Elective and Primary PCI Programs

UMMS supports the requirements that a hospital: (a) obtain a Certificate of Conformance to establish PCI services unless exempted pursuant to the Health General Article and (b) must have provided primary PCI services for a minimum of two years before seeking a Certificate of Conformance for elective PCI services unless it is in a jurisdiction that does not have sufficient access to emergency PCI services. Proposed Md. Code Regs.10.24.17.04A(2) and (3), pg. 11-12. These provisions comport with the governing statute.

Plans of Correction

The terms "approved plan of correction", "acceptable plan of correction" and "accepted plan of correction" are used throughout the sections on Closure of Programs and Certificate of Ongoing Performance. Proposed Md. Code Regs. 10.24.17.04B, pgs. 12-13; 10.24.17.07A(5)(c),(d) and (e) pgs. 24-25; 10.24.17.07B(5)(c),(d) and (e), pgs. 27-28; and 10.24.17.07C(6)(c), (d) and (e), pg. 33. These terms are ambiguous and undefined. The term "acceptable" should be stricken throughout. There should be some clarity as to the standards to be addressed in the plan, who will approve the plan and the process for arriving at an "approved". Moreover, the MHCC should allow adequate time for an appropriate plan to be developed and should require that a plan be submitted, when appropriate, in 60 versus 30 days, as currently proposed.

Program Closure

Cardiac Surgery

UMMS supports the Commission's language that a cardiac surgery program will be "evaluated" for closure under certain circumstances rather than automatically subject to program closure. Proposed Md. Code Regs. 10.24.17(04), pg. 12. We suggest, however, that there should be clarity as to which entity or entities would evaluate conformance with any performance standards under these regulations.

The section on cardiac program closure should make clear that a hospital has a right and "adequate time and opportunity" to address any identified program deficiencies before closure is considered. If closure is considered under subsections 10.24.17(04)(a), (b) or (c), (pgs.12-13), it should be clear that the hospital also has had an opportunity to address deficiencies. To accomplish this, at a minimum, the MHCC should insert the word "and" after subsection (c). Subsection (d) should also be amended to include the words "adequate time and opportunity" to address deficiencies.

The regulations are unclear whether a hospital that loses its CON or Certificate of Ongoing Performance also automatically losses its opportunity to perform PCI services. It should be clear that cardiac surgery and PCI will be evaluated independently should closure become a consideration.

Relocation of Programs

Cardiac Surgery

Section 10.24.17.04C(1)(a), pg. 13, should be eliminated. This section seems to require a hospital seeking to relocate a cardiac surgery program to not only meet all of the requirements of the relocation CON and obtain new Certificates of Ongoing Performance for both cardiac surgery and PCI. The CAG did not entertain a discussion of these issues; therefore, it is important that the intent of this section is made clear. It appears that this section is unnecessary since the hospital seeking to relocate would already have either a new CON for cardiac services or an existing

Certificate of On-going Performance for PCI. If this section is retained, the language should be patently clear as to the specific requirements imposed herein.

Elective and Primary PCI Services

Subsection (2) in Closure of Programs, pg. 13, imposes a similar burden when a hospital with primary and/or elective PCI services seeks to relocate. It would require that the hospital comply with the requirements of a relocation CON and obtain a new Certificate of Conformance for each PCI service. There are multiple concerns here. First, many hospitals are already exempt from obtaining a Certificate of Conformance by virtue of their seasoned, quality PCI programs. This requirement would relegate them to the status of a new, untested program. Second, this requirement is unnecessary since the hospital already has a Certificate of Conformance (or is exempt) and possibly a Certificate of On-going Performance. Third, it seems burdensome to require separate, distinct Certificates for each PCI service.

Peer Review

UMMS is concerned about the impact of the annual peer review provisions in the proposed regulations. Proposed Md. Code Regs. 10.24.17.07A(4), pg. 23; 10.24.17.07B(4), pg. 26 and 10.24.17.07(5), pg. 31. The external review of five (5) percent cases is burdensome and extremely costly. Review of even one case can cost thousands of dollars.

UMMS recommends: "Internal review of 10 randomly selected cases annually for measures of quality, safety, indications, patient satisfaction and review of the relevant cardiac catheterizations and imaging studies. Any case deemed to be outside of the standard of care will be submitted for external review. Any case found to be below the standard of care by external review panel will be reported to the Commission for further consideration."

Certificate of Conformance

As proposed, pursuant to Proposed Md. Code Regs. 10.24.17.04A(2)(c) and (3)(b), pg. 12, the MHCC will publish a review schedule for consideration of new elective and primary PCI programs. With regard to elective PCI programs, the proposed regulations state that the review schedule will be published "at least annually" in each region where there is at least one hospital that provides only primary PCI services. 10.24.17.04(2)(c), pg. 12. With regard to primary PCI, the proposed regulations state that the review schedule will be "published periodically". It would be instructive if the Commission would clarify whether the application process for new elective and primary PCI programs will occur only once per year or whether there will be several application cycles over the course of each year.

Certificate of Ongoing Performance

There are a few issues related to the mechanics of the Certificate of Ongoing Performance that should be clarified. It is unclear how long after a hospital obtains a Certificate of Conformance for PCI it will be subject to review for a Certificate of Ongoing Performance. It should also be clear that a hospital may "renew" its Certificate of Ongoing Performance before the expiration date.

According to the proposed regulations, a Certificate of Ongoing Performance for cardiac services or PCI may be granted for up to five years; a shorter period may be determined at the "discretion" of the MHCC. Proposed Md. Code Regs. 10.24.17.07A(1), pg. 22; 10.24.17.07B(1), pg. 25; and 10.24.17.C(1), pg. 29. Firm criteria should be in place for granting a Certificate for a period of time less than five (5) years, so that decisions of this import are made consistently and with good cause.

The proposed regulations also state that the Commission "may require the successful and timely completion of an "acceptable plan of correction" before a hospital is granted a Certificate of Ongoing Performance" for cardiac surgery or PCI services. Proposed Md. Code Regs. 10.24.17.07A(5)(d), pg. 24; 10.24.17.07B(5)(d), pg. 27 and 10.24.17.07C(6)(d), pg. 33. The Commission should set forth standards for when such a requirement would be imposed.

Cardiac Surgery

As proposed, each cardiac surgery program must participate in uniform data collection and reporting; namely, the STS-ACSD registry. Proposed Md. Code Regs. 10.24.17.07A(3), pg. 23. However, some hospitals in Maryland do not currently participate in that registry. The regulations should provide a grace period for entry in the STS-ACSD registry and, as noted earlier, the data collected therein should be considered prospectively.

The subsection on performance standards begins with a statement that hospitals shall maintain "a composite score of two stars of higher." Proposed Md. Code Regs. 10.24.17.07A(5)(a)(i), pg. 24. Cardiac surgery program scores may vary from time to time, yet the program may still be a quality cardiac surgery program. UMMS recommends that the Commission strike the first part of subsection (i) and begin the subsection with the issue of the one star rating. As revised, Section 10.24.17.07A(5)(a)(i) should read: "If a composite score from the STS-ACSD registry is one star for four consecutive six-month reporting periods the program shall be evaluated for closure", (emphasis added), consistent with 10.24.17.04B, as noted above.

Subsection 10.24.17.07A(5)(b) states that "a hospital with a risk-adjusted mortality rate for cardiac surgery services that exceeds the statewide average beyond the acceptable margin of error..." is subject to a focused review, pg. 24. This may mean that as many as half of the state's programs would consistently be under focused review. It is doubtful that this is the intent. Moreover, confidence intervals can vary greatly for small volume programs, an issue which is addressed by the STS-ACSD Star rating system. Finally, this subsection does not differentiate between different types of cardiac surgery cases, as it should to be meaningful. This subsection should be eliminated or better defined.

Revocation and Voluntary Relinquishment

The proposed regulations are internally inconsistent with regard to the action that the MHCC will take when a cardiac surgery program does not meet the requisite standards. Revocation is suggested in some places; in others the wording suggests "voluntary relinquishment" following a failure to satisfy the terms of a plan of correction. Proposed Md. Code Regs. 10.24.17.07(6)(d). Maryland law permits the MHCC to impose, as a condition of granting a certificate of conformance for PCI services, that the hospital agree to voluntarily relinquish its authority to provide PCI services if it fails to meet applicable standards. MD. ANNOTATED CODE, HEALTH–GEN. II, § 19-120.1(g)(2)(v) (2012). However, there is no similar statutory authority to require a hospital to voluntarily surrender its cardiac surgery program. Also, voluntarily relinquishing a program may compromise a hospital's appeal rights.

Once again, thank you for this opportunity to comment on these draft regulations. We are happy to discuss any of our comments at any time.

Respectfully submitted,

Donna L. Jacobs
Senior Vice President
Government and Regulatory Affairs